10/031922

Cofc

Vinson&Elkins

Reese P. McKnight rmcknight@velaw.com
Tel 512.542.8431 Fax 512.236.3267

October 2, 2006

CERTIFICATE OF MAILING

I certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Attn: Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

October 2, 2006
Date

Reese McKnight

Attn: CERTIFICATE OF CORRECTIONS BRANCH
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U. S. Patent No. 7,109,161 (Patent Application Serial No. 10/031,922) entitled "Preserved Pharmaceutical Formulations," by Atef Gayed
(Our Ref: MAR618/4-006(A)US/75000)
Confirmation No. 2807

Sir:

A Certificate of Correction is hereby requested. The error in claim 20 is the result of a mistake by the U.S. Patent and Trademark Office.

Enclosed for filing in connection with the above-referenced Letters Patent are:

1) Request for Certificate of Correction;

2) An original Certificate of Correction;

3) Copy of Petition to Withdraw from Issue Under 37 C.F. R. § 1.313(c) and Amendment filed July 25, 2005;

4) Copy of U.S. Patent and Trademark Office's Decision granting Petition mailed August 2, 2005

5) Copy of Notice of Allowance mailed August 10, 2005; and,

6) A return postcard to acknowledge receipt of these documents. Please date stamp and mail this postcard upon receipt.

No fees are believed to be due with respect to the filing of this paper. If any fees should be deemed to be due for any reason under 37 C.F.R. §§ 1.16-1.21, the Commissioner is hereby authorized to deduct said fees from Vinson & Elkins Deposit Account No. 22-0365/MAR618/4-006(A)US/75000.

Respectfully submitted,

Reese McKnight
Reg. No. 58,434

Certificate
OCT 10 2006
of Correction

RPM/cp
Enclosures

750535_1.DOC

OCT 12 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Atef Gayed

U.S. Patent No.: 7,109,161

Issued: September 19, 2006

For: PRESER VED PHARMACEUTICAL FORMULATIONS

Group Art Unit: 1614

Examiner: Raymond J. Henley, III

Confirmation No. 2807

CERTIFICATE OF MAILING

I certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Attn: Certificate of Correction Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450:

October 2, 2006
Date

Reese McKnight

REQUEST FOR CERTIFICATE OF CORRECTION

ATTN: CERTIFICATE OF CORRECTION BRANCH
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This request is for issuance of the accompanying Certificate of Correction pursuant to 35 U.S.C. § 254 and 37 C.F.R. § 1.322. The Assignee seeks to correct a mistake found in claim 20 of the above-identified patent ("the '766 patent"), which is the result of a mistake by the U.S. Patent and Trademark Office ("USPTO").

An original Certificate of Correction is enclosed on form PTO/SB/44.

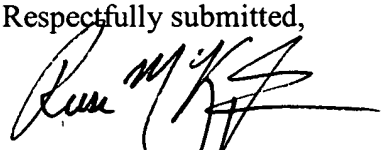
A copy of related correspondence evidencing the mistake is enclosed. Briefly, On July 25, 2005, Assignee withdrew this application from issue and submitted an accompanying amendment. On August 2, 2005, the USPTO withdrew the application from issue acknowledging Assignee's desired amendment. Subsequently, on August 10, 2005, the Examiner issued a Notice of Allowance, and the Notice of Allowance again acknowledged Assignee's desired amendment. It appears however, that the Examiner inadvertently failed to enter the requested amendment to what is now Claim 20. It is this inadvertent mistake by the USPTO which Assignee requests be corrected.

No fees are believed to be due with respect to the filing of this paper. If any fees should be deemed to be due for any reason under 37 C.F.R. §§ 1.16-1.21, the Commissioner is hereby authorized to deduct said fees from Vinson & Elkins Deposit Account No. 22-0365/MAR618/4-006(A)US/75000.

REMARKS

Consideration of the request and issuance of the Certificate of Correction are respectfully requested. The Assignee respectfully submits that the requested correction does not constitute new matter, nor does it require substantive examination of the file.

Respectfully submitted,



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Houston, Texas 77002-6760
Ph: 512.542.8431
Fax 512.236.3267

Date: October 2, 2006

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : **US 7,109,161 B1**

DATED : **September 19, 2006**

INVENTOR(S) : **Atef Gayed**

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

IN THE CLAIMS:

Claim 20

Col. 19, line 19, please delete the comma after scopolomine and delete the word fexofenadine and the comma after the word fexofenadine.

MAILING ADDRESS OF SENDER:

VINSON & ELKINS, LLP
First City Tower
Houston, Texas 77002-6760

PATENT NO. **US 7,109,161 B1**

OCT 12 2006

FORM PTO-1050 (REV. 3-75) (Modified)
 P15/REV01

Vinson&Elkins

Michael J. Smith mjsmith@velaw.com
Tel 512.542.8530 Fax 512.236.3330

July 25, 2005

CERTIFICATE OF Facsimile
37 C.F.R 1.8

I hereby certify that this correspondence is being transmitted by facsimile to the U.S. Patent and Trademark Office pursuant to 37 C.F.R. 1.6(d):

July 25, 2005 | Michael J. Smith
Date

Mail Stop Petitions
Commissioner for Patents
P. O. Box 1450
Arlington, VA 22313-1450

Re: U. S. Patent Application No. 10/031,922 entitled "PRESERVED PHARMACEUTICAL FORMULATIONS" by Atef Gayed
(Our Ref: MAR618/4-006(A)US/75000)

Sir:

Enclosed for filing in the above-referenced patent application are the following:

1. Petition To Withdraw From Issue Under 37 C.F.R § 1.313(c); and

2. Credit Card Payment Form.

The Commissioner is hereby authorized to charge $130.00 as indicated on the attached Credit Card Payment Form. If the enclosed authorization is inadvertently omitted or deficient, or should an overpayment be included herein, the Commissioner is hereby authorized to appropriately deduct or credit the requisite amount from VINSON & ELKINS L.L.P. Deposit Account No. 22-0365/MAR618/4-006(A)US/75000.

Respectfully submitted,

Michael J. Smith
Reg. No. 51,381

102061:3058
Enclosures

610089_1.DOC

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Gayed

Serial No.:10/031,922

Filed: May 13, 2002

For: PRESERVED PHARMACEUTICAL FORMULATIONS

Group Art Unit: 1614

Examiner: Raymond J. Henley III

Atty. Dkt. No.: MAR618/4-6(A)(US)

Confirmation No. 2807

CERTIFICATE OF Facsimile
37 C.F.R 1.8

I hereby certify that this correspondence is being transmitted by facsimile to the U.S. Patent and Trademark Office pursuant to 37 C.F.R. 1.6(d).

July 25, 2005
Date

Michael J. Smith

PETITION TO WITHDRAW FROM ISSUE UNDER 37 C.F.R § 1.313(c)

Mail Stop Petitions
Commissioner for Patents
U.S. Patent and Trademark Office
P. O. Box 1450
Arlington, VA 22313-1450

Sir:

This petition is a request under 37 C.F.R. § 1.313(c) to withdraw from issue the captioned application as Claim 21 is unpatentable under 35 U.S.C. § 112, para. 2 for listing an improper *Markush* group.

Amendments to the Claims are reflected in the listing of claims which begins on page 3.

Remarks begin on page 12.

A credit card authorization is enclosed for the following fee:

Fee Code 1464 (petition under 37 C.F.R. § 1.313) $130.00 USD

No additional fee is believed due, however, if a fee is required for any reason relating to the enclosed materials, the Commissioner is authorized to deduct said fee from Vinson & Elkins LLP Deposit Account No. 22-0365/ MAR618/4-6(A)(US)/75000.

I. AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (previously presented) A pharmaceutical composition comprising a pharmacologically active ingredient and an amount of benzethonium chloride and an amount of phenoxyethanol wherein the amounts of benzethonium chloride and phenoxyethanol are effective to inhibit microbial growth, and wherein said composition is formulated for administration parenterally, by suppository, or orally.

2. (original) The composition of claim 1, further defined as comprising benzethonium chloride in a concentration of from about 0.001 to about 1.0%, and phenoxyethanol in a concentration of from about 0.01 to about 2.0%.

3. (previously presented) The composition of claims 1, 2, or 45, wherein said pharmacologically active ingredient is a cardiovascular agent.

4. (original) The composition of claim 3, wherein said cardiovascular agent is diltiazem, digoxin, dopamine, digitalis, procainamide hydrochloride, lidocaine, verapomil, or levostatin.

5. (previously presented) The composition of claims 1, 2, or 45, wherein said pharmacologically active ingredient is an agent for the treatment of the gastrointestinal system or liver.

6. (original) The composition of claim 5, wherein said agent for the treatment of the gastrointestinal system or the liver is an antacid, a digestant or an emetic.

7. (previously presented) The composition of claim 5, wherein said agent for the treatment of the gastrointestinal system or the liver is lipase, furosamide, morphine, scopolamine, or ranitidine.

8. (canceled)

9. (canceled)

10. (previously presented) The composition of claims 1, 2, or 45, wherein said pharmacologically active agent is a hematologic agent.

11. (original) The composition of claim 10, wherein said hematologic agent is heparin, streptokinase, urokinase, tissue plasminogen activator, or aspirin.

12. (previously presented) The composition of claims 1, 2, or 45, wherein said pharmacologically active agent is an antihistamine.

13. (original) The composition of claim 12, wherein said antihistamine is theophylline, diphenhydramine, hydroxyzine or fexofenadine.

14. (original) The composition of claim 12, wherein said antihistamine is fexofenadine.

15. (original) The composition of claim 14, comprising about 0.005% benzethonium chloride, and about 0.25% phenoxyethanol.

16. (previously presented) The composition of claims 1, 2, or 45, wherein said pharmacologically active ingredient is an antimicrobial.

17. (original) The composition of claim 16, wherein said antimicrobial is penicillin, amoxycillin, kanamycin, neomycin, erythromycin, tetracycline, doxycycline, norfloxacin, or cyclosporin.

18. (previously presented) The composition of claims 1, 2, or 45, wherein said pharmacologically active agent is an antiepileptic or anti-seizure agent.

19. (original) The composition of claim 18, wherein said antiepileptic or anti-seizure agent is phenytoin, dilantin, or phenobarbital.

20. (previously presented) The composition of claims 1, 2, or 45, wherein said pharmacologically active agent is a sedative or hypnotic.

21. (currently amended) The composition of claim 20, wherein said sedative or hypnotic is scopolomine, ~~fexofenadine,~~ or methaqualone.

22. (previously presented) The composition of claims 1, 2, or 45, wherein said pharmacologically active agent is a diuretic.

23. (original) The composition of claim 22, wherein said diuretic is furosemide, amiloride, aminophylline, or theobromide.

24. (previously presented) The composition of claims 1, 2, or 45, wherein said pharmacologically active ingredient is a psychopharmacologic agent.

25. (original) The composition of claim 24, wherein said psychopharmacologic agent is an anti-psychotic or an antidepressant.

26. (previously presented) The composition of claims 1, 2, or 45, wherein said pharmacologically active ingredient is an anti-migraine agent.

27. (previously presented) The composition of claims 1, 2, or 45, wherein said pharmacologically active agent is a hormone.

28. (previously presented) The composition of claims 1, 2, or 45, wherein said pharmacologically active agent is a protein or peptide.

29. (previously presented) The composition of claims 1, 2, or 45, further comprising a second active agent.

30. (previously presented) The composition of claim 29, wherein said second active agent is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial, an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.

31. (previously presented) The composition of claims 1, 2, or 45, wherein said composition is a liquid, suspension, emulsion, solution, mixture, suppository, powder, or tablet.

32. (cancelled)

33. (previously presented) A pharmaceutical carrier composition for use as a carrier of a pharmaceutically active ingredient, wherein said carrier comprises an amount of benzethonium chloride and an amount of phenoxyethanol wherein the amounts of benzethonium chloride and phenoxyethanol are effective to inhibit microbial growth in said composition, and wherein said composition is formulated for administration parenterally, by suppository, or orally by powder, tablet or capsule.

34. (original) The pharmaceutical carrier composition of claim 33, further defined as comprising benzethonium chloride in a concentration of from about 0.001 to about 1.0%, and phenoxyethanol in a concentration of from about 0.01 to about 2.0%.

35. (previously presented) The pharmaceutical carrier composition of claims 33 or 34, wherein said pharmaceutically active ingredient is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial, an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.

36. (previously presented) The pharmaceutical carrier composition of claim 48, wherein said pharmaceutically active ingredient is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial, an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.

37. (previously presented) A vial for containing multiple dosages of a pharmacologically active ingredient, wherein said vial contains a solution comprising said active

ingredient and an amount of benzethonium chloride and an amount of phenoxyethanol wherein the amounts of benzethonium chloride and phenoxyethanol are effective to inhibit microbial growth in said composition, said solution formulated for administration by a route selected from the following: parenteral, suppository, or orally by powder, tablet, or capsule.

38. (original) The vial of claim 37, further defined as comprising benzethonium chloride in a concentration of from about 0.001 to about 1.0%, and phenoxyethanol in a concentration of from about 0.01 to about 2.0%.

39. (original) The vial of claims 37 or 38, wherein said pharmacologically active ingredient is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial, an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.

40. (previously presented) A pharmaceutical package for containing multiple dosages of a pharmacologically active ingredient, wherein said package contains a solution comprising said active ingredient and an amount of benzethonium chloride and an amount of phenoxyethanol wherein the amounts of benzethonium chloride and phenoxyethanol are effective to inhibit microbial growth in said composition, the benzethonium chloride being present in a concentration of about 0.001% to about 0.07%, and the phenoxyethanol being present in a concentration of about 0.01% to about 0.45%, said solution formulated for administration by a route selected from the following: parenteral, suppository, or orally by powder, tablet or capsule.

41. (previously presented) The pharmaceutical package of claim 40, wherein said pharmacologically active ingredient is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial, an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.

42. (previously presented) A method of inhibiting microbial growth in a solution comprising a pharmacologically active ingredient, said method comprising adding benzethonium chloride and phenoxyethanol to said solution wherein said solution is formulated for administration parenterally, by suppository, or orally by powder, tablet, or capsule.

43. (original) The method of claim 42, wherein benzethonium chloride is added in a concentration of from about 0.001 to about 1.0%, and phenoxyethanol is added in a concentration of from about 0.01 to about 2.0%.

44. (original) The method of claims 42 or 43, wherein said pharmacologically active ingredient is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial, an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.

45. (previously presented) A pharmaceutical composition comprising a pharmacologically active ingredient, an amount of benzethonium chloride and an amount of phenoxyethanol, wherein the amounts of benzethonium chloride and phenoxyethanol are effective to inhibit microbial growth, and wherein the benzethonium chloride is present in a

concentration of from about 0.001 to about 0.005%, and the phenoxyethanol is present in a concentration of from about 0.01 to about 0.25% and wherein said composition is formulated for administration parenterally, by suppository, or orally by powder, tablet or capsule.

46. (cancelled)

47. (cancelled)

48. (previously presented) A pharmaceutical carrier composition for use as a carrier of a pharmaceutically active ingredient, wherein said carrier comprises an amount of benzethonium chloride and an amount of phenoxyethanol wherein the amounts of benzethonium chloride and phenoxyethanol are effective to inhibit microbial growth in said composition, and wherein the benzethonium chloride is present in a concentration of from about 0.001 to about 0.005%, and the phenoxyethanol is present in a concentration of from about 0.01 to about 0.25% and wherein said composition is formulated for administration parenterally, by suppository, or orally by powder, tablet, or capsule.

49. (cancelled)

50. (cancelled)

51. (previously presented) A method of inhibiting microbial growth in a solution comprising a pharmacologically active ingredient, said method comprising adding benzethonium chloride and phenoxyethanol to said solution, wherein the benzethonium chloride is added to be in a concentration of from about 0.001 to about 0.005%, and the phenoxyethanol is added to be in a concentration of from about 0.01 to about 0.25% and wherein said composition is

formulated for administration parenterally, by suppository, or orally by powder, tablet, or capsule.

52. (previously presented) The method of claim 51, wherein said pharmacologically active ingredient is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial, an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.

53. (cancelled)

III. REMARKS

Status

Claims 1-7, 10-31, 33-45, 48, 51 and 52 were allowed by the Examiner on April 1, 2005. Applicant paid the issue fee on June 28, 2005.

Claim 21 is unpatentable under 35 U.S.C. § 112, para. 2

In reviewing the allowed claims, Applicant has determined that allowed claim 21 is unpatentable under 35 U.S.C. § 112, para. 2 for listing an improper *Markush* group. Claim 21 as allowed reads:

> 21. The composition of claim 20, wherein said sedative or hypnotic is scopolomine, fexofenadine, or methaqualone.

Fexofenadine is not a hypnotic and was inadvertently listed in claim 21. Its inclusion in claim 21 renders the claim invalid as there is no relationship between fexofenadine and the other listed *Markush* group members. It is not in a recognized physical, chemical, or other art-related class with the other members, nor does it share any common property. Fexofenadine is also not identified in the Specification as a sedative or hypnotic. *See* Specification at p. 18, lines 3-19.

Instead, fexofenadine is a well recognized antihistamine as recited in the Specification at p. 16, line 14. Fexofenadine is further properly claimed as an antihistamine in allowed claims 13 and 14.

In light of the above, the Applicant has amended claim 21 to delete fexofenadine as follows:

> 21. The composition of claim 20, wherein said sedative or hypnotic is scopolomine, ~~fexofenadine,~~ or methaqualone.

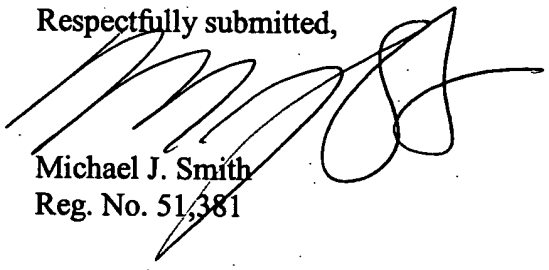
Both scopolamine and methaqualone are recognized sedative or hypnotics as listed in the Specification at p. 18, lines 11 and 18. Thus, the amended claim is patentable.

JUL 12 2005

Conclusion

Based on the remarks above, the Applicant respectfully requests that the present application be withdrawn from issue for consideration of the amendment to claim 21. In addition, based on the amendment of claim 21 and remarks herein, claim 21 is now patentable and in condition for allowance with all other previously allowed claims and such favorable action is respectfully requested. If the Office of Petitions or the Examiner has any questions or comments that might assist in this petition or subsequent reconsideration of the claims, they are invited to contact the undersigned representative at (512) 542-8530.

Respectfully submitted,



Michael J. Smith
Reg. No. 51,381

Vinson & Elkins L.L.P.
2300 First City Tower
1001 Fannin Street
Houston, TX 77002-6760
(512) 542-8530

Date: July 25, 2005

609942_1.DOC

bcc: Paul R. Darkes (w/encl.)
Marya Breig, Docket Coordinator (w/encl.)

****
*** TX REPORT ***
****

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Vinson&Elkins

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Michael Smith mjsmith@velaw.com
Tel 512.542.8530 Fax 512.236.3330

From:	Date:	
Michael Smith	July 25, 2005	
Regarding:	**Number of Pages:**	**Hard Copy Follows:**
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JUL 12 2005

UNITED STATES PATENT AND TRADEMARK OFFICE

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MAR618/4-6(A)CIP

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United States Patent and Trademark Office
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Alexandria, VA 22313-1450
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TIMOTHY S. CORDER
VINSON & ELKINS
2300 FIRST CITY TOWER
1001 FANNIN STREET
HOUSTON, TX 77002-6760

COPY MAILED

AUG 02 2005

OFFICE OF PETITIONS

In re Application of
Atef Gayed
Application No. 10/031,922
Filed: May 13, 2002
Attorney Docket No. MAR618/4-6(A)(US)

DECISION GRANTING PETITION
UNDER 37 CFR 1.313(c)(1)

This is a decision on the petition, filed July 25, 2005, under 37 CFR 1.313(c)(1) to withdraw the above-identified application from issue after payment of the issue fee.

The petition is **GRANTED**.

Petitioner requests that this application be withdrawn from issue "as Claim 21 is unpatentable under 35 U.S.C. § 112, para. 2 for listing an improper *Markush* group."

The petition satisfies the conditions for withdrawal of the application from issue. *Note* 37 CFR 1.313(c)(1). Accordingly, this application is withdrawn from issue.

Petitioner is advised that the issue fee paid on July 1, 2005 in the above-identified application cannot be refunded. If, however, the above-identified application is again allowed, petitioner may request that it be applied towards the issue fee required by the new Notice of Allowance.[1]

Telephone inquiries should be directed to the undersigned at (571) 272-3218.

The file is being referred to Technology Center AU 1614 for appropriate consideration of the amendment and remarks embodied in the petition to withdraw from issue.

Frances Hicks
Frances Hicks
Petitions Examiner
Office of Petitions

---

[1] *The request to apply the issue fee to the new Notice may be satisfied by completing and returning the new Issue Fee Transmittal Form PTOL-85(b), which includes the following language thereon: "Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or re-apply any previously paid issue fee to the application identified above." Petitioner is advised that, whether a fee is indicated as being due or not, the Issue Fee Transmittal Form must be completed and timely submitted to avoid abandonment. Note the language in bold text on the first page of the Notice of Allowance and Fee(s) Due (PTOL-85).*

UNITED STATES PATENT AND TRADEMARK OFFICE

MAR618/4-6(A)US

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

08/10/2005

Timothy S Corder
Vinson & Elkins
2300 First City Tower
1001 Fannin Street
Houston, TX 77002-6760

EXAMINER	
HENLEY III, RAYMOND J	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/10/2005

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,922	05/13/2002	Atef Gayed	MAR618/4-6(A)(US)	2807

TITLE OF INVENTION: PRESERVED PHARMACEUTICAL FORMULATIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$0	$0	$0	11/10/2005

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 07/05) Approved for use through 04/30/2007.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571) 273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

7590 08/10/2005

Timothy S Corder
Vinson & Elkins
2300 First City Tower
1001 Fannin Street
Houston, TX 77002-6760

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,922	05/13/2002	Atef Gayed	MAR618/4-6(A)(US)	2807

TITLE OF INVENTION: PRESERVED PHARMACEUTICAL FORMULATIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$0	$0	$0	11/10/2005

EXAMINER	ART UNIT	CLASS-SUBCLASS
HENLEY III, RAYMOND J	1614	514-002000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are enclosed:

☐ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):

☐ A check in the amount of the fee(s) is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.
NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590 08/10/2005

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Houston, TX 77002-6760

EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/10/2005

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

PTOL-85 (Rev. 07/05) Approved for use through 04/30/2007.

Notice of Allowability

Application No.	Applicant(s)	
10/031,922	GAYED, ATEF	
Examiner	**Art Unit**	
Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the Withdrawal from Issue and Amendment filed July 25, 2005*.

2. ☒ The allowed claim(s) is/are *1-7, 10-31, 33-45, 48, 51 and 52*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date ~~07/12/2006~~. 08042005
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

OCT 12 2006

RAYMOND HENLEY III
PRIMARY EXAMINER
AU 1614

S-00

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michael J. Smith on March 10, 2005.

The application has been amended as follows:

In the Specification:

At page 1 of the specification, before "I. Description of the Invention", the following has been inserted:

---This application is a 371 of PCT/US00/20040, filed July 21, 2000, which claims benefit of U.S. Provisional Application No. 60/228,815, filed July 22, 1999.---.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

August 4, 2005

Examiner-Initiated Interview Summary

Application No.	Applicant(s)	
10/031,922	GAYED, ATEF	
Examiner	**Art Unit**	
Raymond J. Henley III	1614	

All Participants:

(1) *Raymond J. Henley III*.

(2) *Michael J. Smith*.

Status of Application: *Pending*

(3) _____.

(4) _____.

Date of Interview: *10 March 2005*

Time: *AM (e.s.t.)*

Type of Interview:
- ☒ Telephonic
- ☐ Video Conference
- ☐ Personal (Copy given to: ☐ Applicant ☐ Applicant's representative)

Exhibit Shown or Demonstrated: ☐ Yes ☒ No
If Yes, provide a brief description:

Part I.

Rejection(s) discussed:
N/A

Claims discussed:
N/A

Prior art documents discussed:
N/A

Part II.

SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:
Authorization given for Examiner's amendment.

Part III.

☒ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability.

☐ It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.

(Examiner/~~SPE~~ Signature)

(~~Applicant/Applicant's Representative Signature – if appropriate~~)